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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,408	01/04/2002	David Wallach	WALLACH=17A	3196
1444	7590	03/30/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/035,408	Applicant(s) WALLACH ET AL.	
	Examiner Janet L. Andres	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-36 and 39-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-36, 39 and 42-49 is/are allowed.
- 6) ☒ Claim(s) 40, 41, 50-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 7 January 2004 is acknowledged. Claims 34-36 and 39-55 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to claims 38 and 39 is withdrawn in response to Applicant's cancellation of claim 38 and amendment to claim 39 so that it no longer depends from a rejected claim.

3. The rejection of claims 34-37, 40, and 41 under 35 U.S.C. 103(a) as unpatentable over Trataglia, Hsu, or Stanger in view of Song is withdrawn in response to Applicant's amendment restricting the claims to NGF-R, ankyrin 1, and MORT-1 (FADD).

4. The rejection of claims 34-36, 40, and 41 under 35 U.S.C. 112, first paragraph, as lacking written description for all death domains is withdrawn in response to Applicant's amendment restricting the claims to NGF-R, ankyrin 1, and MORT-1.

5. The rejection of claims 34-36, 40, and 41 under 35 U.S.C. 112, first paragraph, as lacking enablement for all death domains is withdrawn in response to Applicant's amendment restricting the claims to NGFR, ankyrin 1, and MORT 1.

New Grounds of Rejection

6. Claims 40, 41, and 50-55 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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These claims encompass methods of producing proteins identified by a screening process. In order to make such proteins, they must first be identified. While methods for identification are set forth, no proteins are identified other than the death-domain containing proteins themselves, which appear able to associate with each other (pp. 71-72). One of skill in the relevant art would not conclude that Applicant was in possession of the genus of death-domain binding proteins. As Applicant states on p. 35 (lines 4-9), this is a large group of proteins or peptides. No common structural features are required or disclosed; all that is required is that they bind the death domain of NGF-R, MORT-1, or ankyrin 1. There is further no indication that this method was actually implemented to identify any binding proteins. The skilled artisan thus cannot envision the detailed chemical structure of the encompassed genus of polypeptides, regardless of the complexity or simplicity of the methods of identification and production. Thus, since Applicant is not in possession of the genus of death-domain binding proteins, Applicant is not in possession of methods of producing them.

7. Claims 40, 41, and 50-55 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of producing NGF-R, ankyrin 1, and MORT-1, does not reasonably provide enablement for producing death-domain binding proteins as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

These claims are drawn to, or encompass, methods of producing proteins identified by a screening method. As stated above, Applicant is not in possession of these proteins. No structural characteristics are defined and the essential properties cannot be envisaged. Since the

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specification does not provide any guidance or any working examples other than the example that shows that the death-domain proteins themselves associate, it is not possible to produce these proteins. An assay for finding a product is not equivalent to a positive recitation of how to make a product, regardless of the ease of screening. Thus it would require undue experimentation to produce the proteins as claimed.

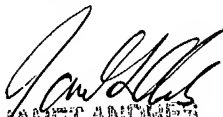
CLAIMS 34-36, 39, AND 42-49 ARE ALLOWED. CLAIMS 40, 41, AND 50-55 ARE REJECTED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization to which this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D
29 March 2004


JANET ANDRES
PATENT EXAMINER